

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of the effect of Non-steroidal analgesics alone with Loratadine combined with Non-steroidal analgesics in the prevention of pain caused by Granulocyte colony stimulating factor in cancer patients

Protocol summary

Study aim

Comparison of the effect of Non-steroidal analgesics alone with Loratadine combined with Non-steroidal analgesics in the prevention of pain caused by Granulocyte colony stimulating factor in cancer patients

Design

Clinical trial with control group, with parallel groups, not blinded. The study phase is 3. Simple randomization using the Graphpad site is used. The study is performed on 70 cancer patients undergoing chemotherapy in two groups. One group received Naproxen and Loratadine and the other received Naproxen.

Settings and conduct

It is performed at Shahid Rajaei Training Center in Karaj. The first group will receive Naproxen 500 milligram (mg) twice daily with Loratadine 10 mg once daily and the second group will receive Naproxen 500 mg twice daily for 8 days after receiving Granulocyte colony stimulating factor. Pain severity after receiving Naproxen and Loratadine is measured based on McGill pain questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria include age 18 or older, presence of malignancy confirmed by pathological reports and receiving chemotherapy drugs and Granulocyte colony stimulating factor; and non-inclusion criteria include history of chronic pain, bleeding or gastrointestinal ulcer, hypersensitivity to antihistamines.

Intervention groups

The first group will receive Naproxen with Loratadine and the second group will receive Naproxen for 8 days after receiving Granulocyte colony stimulating factor.

Main outcome variables

Pain severity due to Granulocyte colony stimulating factor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190922044848N1**

Registration date: **2019-10-05, 1398/07/13**

Registration timing: **retrospective**

Last update: **2019-10-05, 1398/07/13**

Update count: **0**

Registration date

2019-10-05, 1398/07/13

Registrant information

Name

Fateme Atefrad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8840 7199

Email address

m.assadi@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-11, 1397/08/20

Expected recruitment end date

2019-03-11, 1397/12/20

Actual recruitment start date

2018-11-19, 1397/08/28

Actual recruitment end date

2019-03-16, 1397/12/25

Trial completion date

2019-04-09, 1398/01/20

Scientific title

Comparison of the effect of Non-steroidal analgesics alone with Loratadine combined with Non-steroidal analgesics in the prevention of pain caused by Granulocyte colony stimulating factor in cancer patients

Public title

The effect of Loratadine and Naproxen on prevention of pain caused by Granulocyte colony stimulating factor in cancer patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are 18 years of age or older Patients with malignancy confirmed by pathological reports Patients receiving chemotherapy drugs and Granulocyte colony stimulating factor

Exclusion criteria:

Patients with a history of chronic pain Patients with a history of gastrointestinal bleeding or ulcers Patients who have a history of intolerance or hypersensitivity to antihistamines

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Actual sample size reached: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization was performed using the random sequence created by the graphpad site.(<https://www.graphpad.com/quickcalcs/randomize1>) It is an individual randomization unit. Allocation concealment was performed using sequentially numbered, sealed, opaque envelopes.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Alborz University of Medical Sciences

Street address

Alborz University of Medical Sciences, West Bou Ali Street, Nabovat Square, Karaj

City

Karaj

Province

Alborz

Postal code

3149969415

Approval date

2018-11-17, 1397/08/26

Ethics committee reference number

IR.ABZUMS.REC.1397.128

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

2

Description of health condition studied

Multiple myeloma

ICD-10 code

C90

ICD-10 code description

Multiple myeloma and malignant plasma cell neoplasms

3

Description of health condition studied

Hodgkin lymphoma

ICD-10 code

C81

ICD-10 code description

Hodgkin lymphoma

4

Description of health condition studied

Follicular lymphoma

ICD-10 code

C82

ICD-10 code description

Follicular lymphoma

5

Description of health condition studied

Non-follicular lymphoma

ICD-10 code

C83

ICD-10 code description

Non-follicular lymphoma

6

Description of health condition studied

Ovarian cancer

ICD-10 code

C56

ICD-10 code description

Malignant neoplasm of ovary

7

Description of health condition studied

Vaginal cancer

ICD-10 code

C52

ICD-10 code description

Malignant neoplasm of vagina

8

Description of health condition studied

Bladder cancer

ICD-10 code

C67

ICD-10 code description

Malignant neoplasm of bladder

Primary outcomes

1

Description

Pain severity due to Granulocyte colony stimulating factor

Timepoint

Measurement of pain severity 9 days after receiving Granulocyte colony stimulating factor

Method of measurement

McGill pain questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 35 cancer patients are randomly assigned into this group. Naproxen 500 milligram twice daily with Loratadine 10 milligram once daily is prescribed orally for 8 days after receiving Granulocyte colony stimulating factor. Loratadine and Naproxen manufactured by Abidi Pharmaceutical Company from Iran are used in the study.

Category

Prevention

2

Description

Control group: 35 cancer patients are randomly assigned

into this group. Naproxen 500 milligram twice daily is prescribed orally for 8 days after receiving Granulocyte colony stimulating factor. Naproxen manufactured by Abidi Pharmaceutical Company from Iran is used in the study.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei Training Center of Karaj

Full name of responsible person

Fariba Rahimi

Street address

Hesarak, Shahid Rajaei Street, Shahid Rajaei Training Center

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Phone

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Email

frahimi110@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Mohammad Noorisepehr

Street address

Vice Chancellor for Research and Technology of Alborz University of Medical Sciences, Saffarian Alley, 45 Meter Golshahr

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Karaj

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Alborz

Postal code

3198764653

Phone

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Email

dr.noorisepehr@abzums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Karaj University of Medical Sciences

Proportion provided by this source

10

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding*empty***Country of origin****Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Karaj University of Medical Sciences

Full name of responsible person

Fateme Atefrad

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Full name of responsible person

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Position

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**Undecided - It is not yet known if there will be a plan to
make this available**Study Protocol**Undecided - It is not yet known if there will be a plan to
make this available**Statistical Analysis Plan**Undecided - It is not yet known if there will be a plan to
make this available**Informed Consent Form**Undecided - It is not yet known if there will be a plan to
make this available**Clinical Study Report**Undecided - It is not yet known if there will be a plan to
make this available**Analytic Code**Undecided - It is not yet known if there will be a plan to
make this available**Data Dictionary**Undecided - It is not yet known if there will be a plan to
make this available